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MEDICARE FACT SHEET

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**Proposed Regulations To Implement the New Medicare Law:
The Next Step Toward Prescription Drug Coverage,
Better Benefits and Lower Costs for Medicare Beneficiaries**

TODAY'S ACTION

The Centers for Medicare and Medicaid Services (CMS) today proposed regulations to provide a voluntary prescription drug benefit in Medicare and new health plan choices, including regional preferred provider organizations (PPOs), to provide better benefits, higher quality care, and substantial cost savings for Medicare beneficiaries. CMS will use public meetings and comments on the regulations to assure that the new benefits are implemented as effectively as possible less than 18 months from now, in January 2006.

BACKGROUND

Two of the most important provisions of the Medicare Modernization Act (MMA) are the new voluntary drug benefit and the enhanced health plan choices in Medicare Advantage. As a result of these new benefits, beneficiaries can get voluntary drug coverage and new support for their existing drug coverage through Medicare, and they can get access to preferred provider organizations (PPOs), which are the most popular health plan choices for non-Medicare beneficiaries.

Providing voluntary improvements in Medicare coverage to enable beneficiaries to reduce their costs of drugs and other medical services is overdue. One-quarter of seniors and people with a disability who are covered by Medicare have no drug coverage today. Millions more face limits and rising costs in the coverage they receive through Medigap, Medicare Advantage, or state Medicaid plans and pharmaceutical assistance plans. Beneficiaries with retiree coverage are worried about its security, with the decline in coverage that has occurred over the past decade.

As a result of the MMA, and the proposed rules issued today, all of these beneficiaries are closer than ever to having the option of new, subsidized voluntary drug coverage, as well as new support to keep their current retiree coverage secure.

In addition to the standard drug benefit, which is available to all beneficiaries with a 75 percent premium subsidy, the MMA and the proposed regulations provide many approaches for beneficiaries to get even more comprehensive coverage. Low-income seniors and people with a

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disability who have limited means – about a third of all people with Medicare – will get access to comprehensive coverage, with no or limited premiums and deductibles and no gaps in coverage. Medicare beneficiaries with retiree coverage will benefit from a set of options to get affordable enhanced coverage, including a new retiree drug subsidy as well as options for employers and unions to wrap around Medicare coverage or offer Medicare-subsidized drug coverage themselves. Beneficiaries who are contributing to their own coverage now can use the new Medicare subsidies to enable them to pay for additional coverage at a lower cost. In addition, states, other individuals, and charitable organizations can contribute towards a beneficiary's out-of-pocket costs and still have those contributions count towards catastrophic coverage.

Beneficiaries will also have access to a variety of modern integrated health insurance plans, including preferred provider organizations (PPOs). These are the most popular health plans for younger Americans who are covered by commercial health insurance plans, but until now have generally been unavailable to people with Medicare, particularly beneficiaries in rural areas.

The new Medicare law and the proposed rules also allow states the flexibility to "wrap around" the comprehensive coverage for certain low-income beneficiaries in addition to providing net savings to states by providing comprehensive coverage for dual-eligible beneficiaries and providing new subsidies for state retiree coverage.

To implement the new law as effectively as possible, CMS and many organizations involved in health care and Medicare will be hosting meetings all across the country to gather information and comments. CMS will also host a series of national phone calls for additional comment, input and information. Comments can also be sent electronically to www.cms.hhs.gov/regulations/ecomments.

IMPACT OF THE PROPOSED REGULATIONS

The proposed regulations include an extensive discussion of the expected impact of the new drug benefit and new health plan choices.

Impact of Medicare Drug Benefit: Enhanced Drug Coverage with Savings for Beneficiaries, States, and Employers

Comprehensive assistance for low-income beneficiaries: Under the proposed rule, it is estimated that nearly 11 million beneficiaries with limited means will participate in the low-income subsidy, receiving substantial additional help from Medicare.

- About 6.4 million "dual eligible" low-income beneficiaries will have no premium or deductible and nominal co-pays of as little as $1 or $3 per prescription. For these beneficiaries, the Medicare benefit will pay, on average, 97 percent of their drug costs. Of the "dual eligible" beneficiaries, about 1.5 million who are institutionalized are totally exempt from cost sharing. They pay no premiums, no deductibles, no coinsurance and no co-payments.

- About 3 million Medicare beneficiaries who are not full-benefit dual eligibles, but whose incomes are less than 135 percent of the federal poverty level ($12,568 for an individual and $16,861 for a couple in 2004) and who have limited assets will also pay only a few dollars per prescription, with no premium or deductible. Medicare will cover 95 percent of their drug costs on average.
- For about 1.5 million beneficiaries with incomes less than 150 percent of the federal poverty level and assets up to $10,000 (or $20,000 if married) in 2006, the Medicare benefit will provide 15 percent co-pays with a sliding-scale premium, covering 85 percent of their drug costs on average.
- The new comprehensive drug benefit is expected to attract more than 1 million beneficiaries with limited means who have been eligible for Medicaid benefits (including QMB and SLMB benefits) but were not previously enrolled, as a result of the high value of the drug benefit and Medicare's unprecedented outreach activities.

Altogether, with the straightforward means test proposed in the rule, about a third of all Medicare beneficiaries are eligible for low-income assistance with no gaps in coverage, and limited or no premiums and deductibles. This coverage is worth almost $3,500 on average and means tremendous savings in drug costs. For example, beneficiaries with incomes below 135 percent of the federal poverty level and meeting the asset test can get a lifesaving drug that costs $40,000 or more for at most $60 per year.

Affordable, voluntary drug coverage for all beneficiaries: All Medicare beneficiaries will have access to a voluntary drug benefit. A typical beneficiary – not eligible for additional low-income benefits – with no coverage today will see their total spending on drugs drop by 53 percent. The savings for the standard drug benefit come from two main sources:

- Beneficiaries will see lower drug costs as a result of price negotiation and coordination of health services by the prescription drug plans and Medicare Advantage plans, which will face strong pressures to keep drug costs low and pass on the savings. The new drug benefit is expected to provide beneficiaries with drug cost savings of 15 percent initially, rising to 23 percent within 5 years. These cost savings are the result of strong competitive pressures, including transparency in drug price and benefit information, for drug plans to negotiate discounted prices and manage drug costs to obtain the lowest costs possible while providing the drugs that beneficiaries need, and to pass these savings on to beneficiaries. The proposed rule outlines an approach similar to the one used by the Federal Employees Health Benefits Program and other large health care payers. This approach is expected to provide the best discounts on drugs – discounts as good or better than could be achieved through direct government negotiation, resulting in prices that will be substantially better than Medicare's prior experience with price regulation for the drugs that it currently covers in Medicare Part B.

- The standard drug benefit in 2006 will pay on average 75 percent of these lower drug costs after a $250 deductible, up to an initial coverage limit of $2,250, and will pay about 95 percent of the beneficiary's drug costs once the beneficiary spends $3,600 out-of-pocket.

There is no annual plan maximum, and that coverage will never run out. On average, beneficiaries will receive a 75 percent subsidy on the premium for this coverage, resulting in a cost of about $35 a month in 2006 (that is, for the first time, Medicare will be paying about $105 a month per beneficiary toward the cost of drug coverage for all beneficiaries).

The subsidy Medicare provides for standard drug coverage can be combined with other sources of assistance to provide even greater coverage. States, charitable organizations, and other individuals can contribute to beneficiary out-of-pocket costs while still having their contributions count as "true" out-of-pocket expenditures. Beneficiaries, employers, and others can use some of their existing contributions to buy supplemental or "high-option" coverage to enhance the standard coverage, while still obtaining substantial overall savings compared to what they or their employer is paying now because of the new Medicare subsidies.

Annual Drug Benefit Savings for a Beneficiary With Typical Drug Spending Today

Beneficiary Group	Annual Spending Today	Out-of-pocket Spending Under Part D	Percentage Savings After Premium	Dollar Savings After Premium
Beneficiary with standard coverage with incomes at or above 150% of FPL	$ 2400	$ 697.50	53%	$1,274.50
Beneficiary with income under 150% FPL and modest assets	$ 2400	$ 348.50	77%	$1,837.50
Beneficiary with income below 135% FPL and low assets	$ 2400	$ 109.85	95%	$2,290.00
Beneficiary dually eligible for Medicaid with income below 100% FPL	$ 2400	$ 62.77	97%	$2,337.23
Beneficiary who is dually eligible for Medicaid and a nursing home resident	$ 2400	$ 0	100%	$2,400.00

Explanatory Notes: $2400 is close to the projected median spending for all beneficiaries in 2006. Beneficiary out-of-pocket and percentage savings assume 15% cost management savings by Part D plans, through price discounts and utilization management. Premium for the 150% FPL group is assumed to be in the middle of the sliding scale between $0 and $428. The out-of-pocket calculation for the 135% FPL and 100% groups assumes an average prescription price of $65 and an average co-pay of $3.50 and $2, respectively. The 77% differs from the 85% that appears elsewhere in the text because the 85% is based on the mean beneficiary spending (the average of spending for all beneficiaries) while the 77% is based on the median beneficiary spending (the spending of the average beneficiary). The 77% also includes premium costs while the 85% includes only out-of-pocket costs.

Savings for a Beneficiary With Annual Spending of $10,000

Beneficiary Group	Annual Spending (Unmanaged, Full Retail)	Out-of-pocket Spending Under Part D	Percentage Savings After Premium	Dollar Savings After Premium
Beneficiary with standard coverage at or above 150% FPL	$10,000	$3,770.00	58%	$5,802
Beneficiary with income under 150% FPL and low assets	$10,000	$990.58	88%	$8795.42
Beneficiary with income below 135% FPL and low assets	$10,000	$274.62	97%	$9725.38
Beneficiary dually eligible for Medicaid with income below 100% FPL	$10,000	$156.92	98%	$9843.08
Beneficiary who is dually eligible for Medicaid and a nursing home resident	$10,000	$0	100%	$10,000

Explanatory Notes: Beneficiary out-of-pocket and percentage savings assume 15% cost management by Part D plans, through price discounts and utilization management. Premium for the 150% FPL group is assumed to be in the middle of the sliding scale between $0 and $428. The out-of-pocket calculation for the 135% FPL and 100% groups assumes an average prescription price of $65 and an average co-pay of $3.50 and $2, respectively.

Support for retiree drug coverage plans: The proposed rule provides new support for retiree drug coverage provided by employers and unions through a set of new options:

- Medicare will provide a retiree drug subsidy for high-quality drug coverage from a beneficiary's former employer or union. Sponsors of qualified retiree prescription drug coverage will receive federal subsidies of 28 percent of incurred allowable drug costs between $250 and $5,000 in 2006 per qualifying covered retiree to help the companies maintain prescription drug coverage for their retirees. The estimated value of this subsidy is $611 per beneficiary in 2006, and for employers with tax liability, the tax-free retiree drug subsidy would be equal to a taxable subsidy of $855 at the average corporate marginal tax rate and $940 at the 35 percent marginal tax rate paid by many large companies.

- Medicare will allow retiree drug plans that meet Medicare's standards to qualify as Part D plans and obtain the Part D subsidy. In this option, Medicare would subsidize the cost of drug

coverage primarily through direct premium subsidies for the enhanced benefit plans, and additionally through reinsurance subsidies for beneficiaries who reach high out-of-pocket expense levels.

- Beneficiaries who receive high-quality coverage through a private, coordinated-care health plan offered only to a firm's retirees can also obtain the Part D subsidy. As in the previous option, Medicare would provide both direct premium subsidies and reinsurance subsidies to these enhanced drug plans.

- Employers and unions may also offer "wrap around" coverage, providing supplemental Part D benefits much like employers and unions commonly do today for Part A and Part B benefits. As in the previous options, Medicare would provide both direct premium subsidies and reinsurance subsidies to these enhanced drug plans.

While the retiree drug subsidy is likely to be the most attractive option to employers and unions, the additional options are important to help ensure that retirees are better off. For example, one of the objectives of the proposed rule is to avoid "windfalls" for employers and unions, those situations in which retirees would receive a smaller subsidy from their retirement plan than Medicare would pay on their behalf. Some employers currently contribute less than the value of the retiree drug subsidy, and while some of these employers may increase their contributions in order to qualify for the alternative subsidy (and thus obtain a net reduction in their retiree benefit costs while providing more generous coverage), others may need to use a different approach to combine their support with the new assistance from Medicare. As another example, some employers may prefer to "wrap around" Part D coverage, providing enhanced benefits on top of Medicare coverage just as they do for Parts A and B, instead of providing a fully separate benefit. The additional approaches use means other than the retiree drug subsidy to reduce the cost to employers who continue to provide as generous or more generous retiree coverage, in order to achieve the maximum increase in support for retiree coverage. Consequently, under all of the options discussed in the proposed rule, the new Medicare support for retiree coverage is expected to result in a net increase in contributions for retiree coverage, with a substantial increase in the generosity of coverage for many retirees due to the MMA.

Large savings in drug costs for rural beneficiaries: The new drug benefit is particularly important for one out of four Medicare beneficiaries who live in rural areas. These beneficiaries are less likely to have inexpensive drug coverage from retiree plans or other sources, and many rural beneficiaries have limited incomes and assets. The new Medicare drug plan is guaranteed to be available in rural areas. The prescription drug plans will serve entire regions, and the proposed rule includes a guaranteed "fallback" program to further ensure that every Medicare beneficiary across the country has access to prescription drug coverage.

Savings for states: States are projected to get net savings of about $500 million in 2006 and $8 billion in the first five years of the drug benefit. Net savings are projected for states that provide Medicaid-only coverage, states with Medicaid and state pharmaceutical assistance plans, and states with Medicaid and "Pharmacy Plus" (Section 1115 waiver) plans. The sources of savings are:

- *Medicare drug coverage for dual eligibles:* Starting in 2006, full-benefit dual eligible beneficiaries (Medicare beneficiaries eligible for a state's full range of Medicaid benefits, including drug coverage) will receive prescription drug coverage through Medicare rather than through their state Medicaid programs.

- *New subsidies for state retiree health programs:* As employers, states can qualify for the new retiree drug subsidies available to employers and unions that furnish qualified retiree drug coverage to Medicare beneficiaries.

- *Relief for State Pharmaceutical Assistance Programs:* States that operate State Pharmaceutical Assistance Programs (SPAPs) and "Pharmacy Plus" waivers providing subsidized drug coverage to individuals who will be eligible for the Medicare prescription drug plan will gain substantial savings starting in 2006, when Medicare begins providing very generous coverage for beneficiaries with limited means. As a result of the savings on beneficiaries who qualify for the low-income Medicare coverage, states can "wrap around" the Medicare benefit to maintain or enhance benefits, at a lower cost to the state.

Recognizing that states no longer will have the obligation to pay for drug coverage for full-benefit dual eligibles, states will be required to make payments to the federal government to defray a portion of the Medicare drug expenditures for full-benefit dual eligibles. States will also face some new administrative costs, though the Social Security Administration expects to provide substantial assistance in enrollment, reducing state administrative burdens. The new drug coverage and outreach are also expected to increase Medicaid enrollment. The net savings for states reflect all of these factors.

Impact of Enhanced Medicare Advantage Program: Greater Access to Coverage with More Benefits and Lower Out-of-Pocket Costs

Availability of more health plan choices that help beneficiaries save money: The proposed rule will increase the availability of coordinated-care health plans through Medicare Advantage that allow beneficiaries to lower their out-of-pocket costs significantly. The savings are possible because the plans generally offer lower cost-sharing as well as additional benefits – including coverage for additional preventive services, disease and care management services, and other services like dental and vision – that are not available in fee-for-service Medicare. As a result, beneficiaries enrolled in Medicare Advantage plans can obtain substantial savings in out-of-pocket costs compared to the traditional fee-for-service Medicare plan.

In 2003, average annual out-of-pocket medical expenses for beneficiaries in Medicare + Choice (the coordinated-care plans that preceded the Medicare Advantage plans) were $667 lower than expenses for beneficiaries in fee-for-service Medicare without subsidized Medigap coverage (coverage from a former employer, Medicaid, or other source that fills in the gaps in Medicare benefits). The Medicare Advantage reforms are expected to increase the opportunities for lower cost sharing and improved benefits in coordinated care plans.

Beneficiaries in poorer health, in particular, will find Medicare Advantage plans to be an attractive option: in May 2004, such beneficiaries enrolled in Medicare Advantage plans had annual out-of-pocket costs that were $1,900 less than beneficiaries in poor health covered by fee-for-service Medicare with no supplemental coverage (based on unpublished CMS data on out-of-pocket costs). Consequently, Medicare Advantage plans have been especially popular for beneficiaries with limited means, and the proposed regulations will enable many more beneficiaries to obtain such savings if they choose to do so.

Expanding health plan choices with regional PPOs. Under the proposed regulations, CMS expects that all parts of the country will be served by regional PPOs. Regional plans will bid to serve entire regions (which may encompass multiple states), providing new access to private plan options and making extra benefits available to rural residents for the first time. PPOs are the most popular type of health plan among non-Medicare beneficiaries. As a result of the new PPO options, beneficiaries will have even more options to lower their out-of-pocket costs and increase their benefits.

DETAILS OF THE PROPOSED REGULATIONS

CMS is seeking comments on all aspects of the MMA regulations for the Medicare prescription drug benefit (including the retiree drug subsidy program) and the Medicare Advantage programs. CMS will conduct multiple public meetings and listening sessions on many of the proposed issues to ensure that the new benefits are implemented as effectively as possible. This section highlights new features in the proposed rules that CMS is working to implement.

The Medicare Prescription Drug Benefit

Choices for Drug Coverage. With increased access to prescription drug coverage as part of Medicare, millions of seniors and people with a disability will be able to purchase more affordable drugs, resulting in better health outcomes.

The proposed rule describes the options that beneficiaries can use to choose how they want to get their outpatient drug coverage. Prescription drug plans and Medicare Advantage plans will be required to provide basic coverage, but may also offer additional plans with supplemental coverage. Such "high option" plans with enhanced coverage (for example, covering 75 percent of drug spending without any gap in coverage) allow beneficiaries to add to the Medicare-subsidized coverage using some of the contributions that beneficiaries, health plans, employers, unions, and others are making today. Charitable organizations, other individuals, and states will also be able to contribute to beneficiary out-of-pocket costs while still having their contributions count as "true out-of-pocket" spending for purposes of the Medicare subsidy for high drug expenses.

Medicare prescription drug plans will be required to have cost management programs that lower prescription drug costs for beneficiaries. CMS is also seeking comments on such issues as how plans can provide alternative coverage that some beneficiaries may prefer within the constraints set by law, how best to structure and support medication therapy management programs, and how best to proceed in constructing a coordination of benefits system that will enable multiple payors to be recognized for individual drug claims.

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Competition and Price Negotiation for Low-Cost, High-Quality Drug Plans. The proposed rule describes a competitive process for getting low premiums, low drug prices, and high-quality pharmacy services for Medicare beneficiaries so that they have access to high-quality prescription drug plans at an affordable price. The process is similar to the approach used by the Federal Employees Health Benefits Program and state governments to give their employees and retirees access to affordable drug coverage that best reflects their own preferences about formularies and other features. The process includes direct Medicare oversight to make sure that the costs and quality of plan "bids" are reasonable. Medicare will also empower and support beneficiaries in "comparison shopping" by providing specific information on premiums, covered drugs and their prices, and pharmacies and pharmacy services. Medicare beneficiaries will pay less for less costly prescription drug plans, providing another incentive for getting the lowest possible drug prices.

Strong competitive pressures mean that plans will have to negotiate lower drug prices aggressively, and pass on savings to beneficiaries. CMS expects drug plans to achieve, on average, a 15 percent cost management savings in 2006, with increasing savings over time. The cost management savings will contribute to the lower out-of-pocket payments for prescription drugs, enabling millions of beneficiaries to purchase prescriptions that they otherwise would not have been able to afford. This competitive approach to obtaining lower negotiated prices is expected to provide the best discounts on drugs – discounts as good or better than could be achieved through direct government negotiation, resulting in prices that will be substantially better than Medicare's prior experience with price regulation for the drugs that it currently covers in Medicare Part B. In addition, beneficiaries will also have formulary coverage and pharmacy services that are more responsive to their own preferences than in a government-run plan.

CMS is seeking comments on steps that will achieve the maximum drug savings possible, without compromising beneficiaries' access to the medicines they need. For example, the proposed rule seeks comment on how to best design the drug benefit information, including personalized information on drug prices and information about formularies and pharmacies so beneficiaries will be able to know how much they will have to pay for their drugs, similar to the information currently provided by Medicare for the Medicare-Approved Discount Drug Card program. As discussed below, CMS is also conducting an extensive process for public input on model formulary classification systems and formulary oversight.

Straightforward Asset Test for Low-Income Assistance. Eligibility for the comprehensive low-income Medicare coverage includes income limits and an asset test. For an effective and straightforward asset test, Medicare proposes counting only liquid assets like financial holdings and bank balances, and real estate holdings other than the homestead. Medicare will not consider the family home, family heirlooms, wedding rings, burial plot, the family car, or any other non-liquid assets in its determination of eligibility for the low-income benefit.

Features to Allow States to Save While Providing More Help for Beneficiaries. The proposed rules also allow states the flexibility to establish State Pharmaceutical Assistance Programs (SPAPs) to "wrap around" the prescription drug coverage under Medicare for beneficiaries who do not have comprehensive coverage. SPAP assistance with beneficiary cost sharing would count toward the out-of-pocket catastrophic threshold. As a result, SPAPs will be able to

continue to provide as generous or more generous assistance for the beneficiaries who receive coverage through state programs now, at a lower cost per beneficiary for the states because of the availability of the Medicare drug benefit. States will also be able to restructure existing "Pharmacy Plus" programs to wrap around the Medicare prescription drug benefit.

Medicare intends to work closely with states, through comments, the new "SPAP Commission" and many other forums, to ensure that the drug benefit delivers better coverage and lower costs for beneficiaries based on the individual circumstances of each state.

Increased Support for Retiree Coverage. The proposed rule offers employers and unions a variety of options to provide enhanced, subsidized coverage for their Medicare retirees that is as generous or more generous than the coverage provided today – at a lower cost to the employer or union and the beneficiary as a result of the Medicare retiree drug subsidy and other types of new Medicare assistance for high-quality retiree coverage. First, employers and unions that provide qualified retiree prescription drug coverage can receive a retiree drug subsidy for beneficiaries who do not enroll in a Medicare prescription drug plan. As proposed, this subsidy has highly flexible rules that permit employers and unions to continue providing their current drug coverage at a lower cost, if it is at least actuarially equivalent to the standard prescription drug benefit. The proposed rule seeks comment on several options for defining actuarial equivalence under the new rule. While all of the definitions would avoid employer "windfalls" – that is, plans in which employer contributions to the drug benefit are smaller than the retiree drug subsidy payment from Medicare – they may have different implications for employer choices of using the retiree subsidy or other approaches to provide enhanced retiree coverage.

In addition, employers can also provide enhanced retiree drug coverage over and above the standard prescription drug benefit through or in coordination with a Medicare prescription drug plan, with Medicare subsidizing the costs of their standard prescription benefits. This may be achieved by:

- providing supplemental drug coverage that wraps around a prescription drug plan (similar to policies that wrap around Medicare benefits under Part A and Part B),
- providing an employer-sponsored Medicare Advantage or Medicare prescription drug plan to provide enhanced benefits to their retirees, or
- choosing to become a Part D plan that offers enhanced benefits to their retirees.

In all of these cases, financial support from the new Medicare drug subsidy augments contributions by employers, to provide a more generous and less costly drug benefit for retirees than has been possible through employer support alone.

The proposed rule notes that, while overall support for retiree coverage will increase significantly under all of the options included in the regulation, there are a number of specific ways in which each of these coverage options may be implemented that has consequences for how retirees get enhanced, subsidized coverage, whether through the retiree drug subsidy or through one of the other enhanced-coverage options. The rule outlines specific areas for comment and requests data on how to maximize retiree coverage, while limiting the total cost of the subsidies to the government.

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Medigap Options and Supplemental Coverage. While Medigap policies with drug coverage will no longer be issued to new subscribers after January 1, 2006, insurers will be able to continue to supplement Medicare's Part A and Part B benefits for beneficiaries. Medigap beneficiaries who have existing drug coverage under a Medigap plan will be able to continue that coverage. However, beneficiaries would pay the full cost of the premium for Medigap drug coverage (often over $120 a month for the drug coverage portion of the Medigap plan, versus the $35 a month Part D premium), the standard Medigap plans offer only limited drug coverage with no catastrophic protection, and beneficiaries would face a late enrollment penalty if they enroll in a prescription drug plan after the six-month open enrollment period. So it is likely to be much more advantageous for beneficiaries to enroll in the subsidized, more generous Medicare prescription drug plan.

Under the proposed rule, beneficiaries who enroll in a prescription drug plan may also be able to purchase expanded drug coverage from a prescription drug plan or Medicare Advantage plan in addition to Medicare's basic coverage. This expanded coverage is referred to as supplemental benefits. In meeting the requirement of providing basic coverage, Medicare Advantage plans that provide drug coverage may also offer a plan including supplemental coverage, if the supplemental coverage can be offered at no additional premium. (A Medicare Advantage organization that offers a plan that includes supplemental coverage at no additional cost also may offer other "higher option" plans that offer supplemental coverage at an additional cost.)

Beneficiary Protections. The proposed rule also describes protections to make sure that beneficiaries have coverage for medically necessary drugs through nearby pharmacies.

Prescription drug plans would be subject to many of the existing beneficiary protections that are available in Medicare, as well as some new ones, including requirements to meet strict pharmacy access standards to give beneficiaries access to retail pharmacies and needed drugs.

The proposed rule also describes how the drug benefit will build on the transparent pricing and drug coverage features of the Medicare Drug Discount Card Program, with the goal of making sure that beneficiaries can get the specific, personalized information they may want about a plan's prices, formularies (specific covered drugs), and included pharmacies.

The rule also outlines approaches to assure access to necessary drugs at an affordable benefit cost through drug formulary standards and oversight. When possible, plans will be required to include multiple drugs in every therapeutic category on their formularies. Plans must encourage the use of generic drugs by requiring provision of information on lower cost generic substitutions (if available) at the point of sale. Plans must use a pharmacy and therapeutics committee including practicing doctors and pharmacists to establish a formulary, so plan enrollees can be assured that they have access to the most up-to-date drugs possible.

Medicare also proposes to use a model formulary classification system developed by US Pharmacopeia as a "safe harbor" for meeting Medicare's formulary classification requirements, and is soliciting comments on other steps to encourage "value-based" formularies. Medicare will hold a public meeting in August to discuss the specific details of the preliminary USP "model guidelines for formulary categories and classes."

The proposed rule outlines the process for covering a drug that is not on the formulary when a physician determines that it would be in the best interest of the patient to have that drug. Under this process, urgently needed drugs would be covered while a prompt exception process is completed. Beneficiaries can be helped in the appeals process by their physician or an authorized representative (often a family member or caregiver).

Plans offering the new Medicare drug benefit will also be required to have a program to make sure beneficiaries receive the appropriate drugs to improve their health outcomes and reduce adverse drug interactions. Plans will be required to supply a range of useful information to beneficiaries, including a clear explanation of the benefits and periodic status reports on other prescription drug spending; a description of the function of any formulary; useful information about how the use of generic drugs can help to lower drugs costs even more; how the plan's medication management program works; and information on grievance and appeals processes.

Plans must also maintain beneficiary privacy and confidentiality, and conduct surveys on customer satisfaction.

Electronic Prescribing and Quality Improvement. To lower drug costs and improve quality, the proposed rule requires drug plans to support electronic prescribing, and CMS intends to accelerate the implementation of electronic prescribing through the Medicare drug benefit. CMS expects to issue proposed regulations related to electronic prescribing standards that have broad support, and identify promising e-prescribing pilot programs this fall. CMS is seeking comment on ways to accelerate the adoption of e-prescribing further, and to reduce costs by adopting e-prescribing, as well as comments on how Medicare electronic prescribing can further national health IT goals.

As discussed above, prescription drug plans and Medicare Advantage plans will be required to establish pharmacy and therapeutics committees that include practicing pharmacists, physicians and an expert in geriatric care. The committees will use the best scientific evidence on the safety, efficacy and side effects of drugs to enhance the quality of the drug plans while controlling costs for beneficiaries.

Improved Medicare Advantage Plans

The proposed changes in the Medicare Advantage program are expected to increase not only the number and stability of plans participating in Medicare managed care, but also to increase the types of plans, including regional PPOs. Additionally, CMS is proposing reforms to various procedures that will make the Medicare Advantage program function more like the Federal Employees Health Benefits Program, with plans better able to tailor their services to their enrollees' needs while reducing administrative costs.

Competitive Bidding for Health Plans for Part A and B Benefits. Both the regional PPOs, which must serve all of a CMS-designated region, and the local Medicare Advantage plans, which cover single or multi-county areas they choose to serve, use the same bidding process for Part A and B benefits. Following a market survey with extensive public input that is currently being

conducted, the Secretary will establish 10 to 50 Medicare Advantage PPO regions, designed to maximize plan participation. Medicare has presented a specific set of options for public discussion and comment for defining regions for both drug plans and regional PPOs.

Plans may offer a PPO in more than one region or in all regions. The goal of these larger regional markets is to have more plan options in rural areas by grouping them with the urban areas that have traditionally attracted managed care plans under the Medicare + Choice program.

The Medicare Advantage local and regional plans will both have a new model for bidding and payment. Under this model, plans will submit bids for how much it would cost them to provide medical benefits to a "typical" beneficiary in the region or service area, where a typical beneficiary has the statistical average age and health status for Medicare beneficiaries in the nation. Medicare payments to a plan will depend on the benchmark determined by the competitive bidding process. The Medicare benchmark for local and regional plans is the most that Medicare will pay for Medicare Part A and Part B services. The Medicare benchmark for regional plans is based on a model that blends the current administered pricing system for local plans with an average of regional plan bids for the typical beneficiary in that region. For plans with bids that are less than the benchmark, the beneficiary gets three-fourths of the difference in the form of lower premiums or cost sharing or additional benefits, and the government retains one-fourth. For plans with bids that are higher than the benchmark, beneficiaries pay the difference in the form of a premium. Consequently, more efficient plans can attract beneficiaries through lower premiums or alternatively, they can use the beneficiary savings to offer additional benefits.

In setting the benchmarks, the rule includes the changes under the MMA to provide more accurate and fair Medicare Advantage county capitation rates in many counties. The new funding is expected to help ensure that Medicare beneficiaries who count on Medicare Advantage plans will have reliable access to them, and consequently to the additional benefits and significantly lower out-of-pocket costs generally provided by these plans. The new funding in 2005, announced in May 2004, is also likely to bring additional Medicare Advantage plans into more markets serving more Medicare beneficiaries, so that more beneficiaries have access to lower-cost, higher-benefit coverage options.

By enhancing the use of risk adjustment methods to pay health plans, CMS intends to concentrate new Medicare Advantage funding on beneficiaries who are expected to need it the most based on their health status, ensuring that regardless of beneficiaries' specific health status, they will benefit from the wide range of available choices. CMS is refining the risk adjustment methodology currently used to pay Medicare Advantage plans to improve its ability to provide higher payments for beneficiaries with complex conditions. CMS is also working on developing a risk adjustment payment methodology for the new drug benefit plans and will be seeking further comment.

Medicare is seeking comments on a number of technical issues related to the specifics of determining the components of the payment process for all Medicare Advantage plans, such as the determination of the risk-adjusted benchmark and the Medicare Part A and Part B bid amounts. These include use of statewide versus plan-specific risk adjustment for determining rebate amounts; how to adjust regional and local plan payments for intra-area variation in

payment rates; and how to address the requirement that beneficiary cost-sharing for Part A and Part B benefits be actuarially equivalent to the average monthly cost sharing in fee-for-service Medicare.

Access to Plans in Rural Areas. The new regional PPOs are expected to bring Medicare Advantage plan options to beneficiaries in rural areas. Regional plans will bid to serve entire regions to provide access to private plan options and make extra benefits available to rural residents for the first time. The proposed rule includes several tools to attract and retain regional PPOs, including start-up risk corridor payments, an entry and retention fund, and special payments to essential hospitals treating regional plan enrollees.

The new Medicare drug plan is guaranteed to be available in both urban and rural areas. Like the regional Medicare Advantage plans, prescription drug plans will serve entire regions. Although Medicare does not project that fallback plans will be necessary, the proposed rule includes a guaranteed fallback program to further ensure that every Medicare beneficiary across the country has access to prescription drug coverage.

Other New Beneficiary Products. The proposed rule also describes the new specialized plans authorized by the MMA for Medicare beneficiaries who have special needs. This new option is available through December 31, 2008, for plans that exclusively or disproportionately enroll these individuals. The law specifies two special needs groups: the institutionalized and Medicare beneficiaries who also have Medicaid coverage. The law permits the designation of other chronically ill or disabled beneficiaries as special needs individuals who could be served by specialized plans. CMS is seeking comment on how to define these individuals.

The proposed rule also addresses changes to the existing provisions for Medical Savings Accounts for Medicare beneficiaries. Among other changes, the rule makes permanent the Medical Savings Accounts option, and it eliminates the cap on the number of beneficiaries that may enroll in a Medicare Savings Account.

Quality Improvement. By 2006, each Medicare Advantage plan (other than an Medicare Advantage private fee-for-service plan or an MSA plan) will be required to have an ongoing chronic care improvement program and quality improvement program. Under the quality improvement program, both local and regional Medicare Advantage plans are required to provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality.

More Personalized Assistance to Help Beneficiaries Get the Most Out of the New Benefits

CMS has taken many steps to increase the beneficiary assistance available, and seeks comments on how to further improve our ability to help beneficiaries get the personalized assistance they need to get the most out of Medicare's expanded benefits and out of our increasingly modern, but increasingly complex health care system. These steps build on recent enhancements at 1-800-MEDICARE, so beneficiaries can get additional support in identifying the best drug plans and health plan options for their needs. CMS has increased the number of customer service operators from several hundred to 3,000 as of the beginning of June 2004, and expects to

maintain this number of trained representatives to handle the unprecedented number of callers in a timely and effective manner. CMS has added voice messages to help callers be better prepared when they reach a customer service representative, further reducing call waiting and call handling time.

CMS also intends to continue and enhance the use of informational mailings to help beneficiaries understand the new Medicare benefits and how to get the most out of these benefits. These publications will also be available online at www.medicare.gov.

For beneficiaries who require or prefer face-to-face personalized assistance, CMS has also enhanced its partnership with the State Health Insurance Assistance Programs (SHIPs). CMS recently announced that HHS will award $21.1 million this year and another $31.7 million next year to the SHIPs, thereby reflecting the increased emphasis on one-on-one advice and counseling for Medicare beneficiaries. The SHIPs are among the most effective resources in helping beneficiaries learn about the changes to Medicare and will be able to use the additional funds to equip local organizations with the tools needed to answer beneficiaries' questions. CMS is also supporting non-profit organizations to help educate and assist low-income beneficiaries who may otherwise be hard to reach. CMS is seeking comments on how to use communications tools like the Internet and telephone support systems, as well as SHIPs and private organizations and other approaches, to further improve our personalized outreach and support.

Public Comments and Public Listening Sessions

Since Medicare will be offering far more comprehensive and up-to-date benefits than ever before, CMS is seeking public comment, information, and input to help us implement the law on time, as effectively as possible, and to bring overdue assistance with drug costs and other modern medical benefits to the Medicare program. CMS and many organizations involved in health care and Medicare will be hosting meetings all across the country to gather this information within the designated timeframe. There will also be a series of national phone calls and if you want to submit any comments, concerns, or ideas about how to make the program better, you can contact CMS at www.cms.hhs.gov/regulations/ecomments.

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